

Present Claims 22-34 relate to methods for producing cheese, which comprise:

- (1) mixing a partial hydrolysate of milk whey protein with a milk material, to obtain a first mixture;
- (2) treating said first mixture with transglutaminase, to obtain a second mixture; and
- (3) coagulating said second mixture with a milk coagulating enzyme, to obtain a mixture comprising cheese curd and whey.

The inventors have found that the presently claimed methods exhibit a surprisingly enhanced yield of cheese as compared to conventional methods for preparing cheese.

The cited references contain no disclosure or suggestion of such a method of preparing cheese. Moreover, these references contain no teaching which would suggest the improved yields afforded by the presently claimed methods. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 8-34 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 6,224,914 (Han et al) in view of Monti et al is respectfully traversed. Han et al discloses a process in which a milk product, fortified with whey protein, is first treated with transglutaminase, to effect cross-linking of the whey protein, and then added to another milk product for curding. Thus, what is added to the milk in the process in Han et al is a ***cross-linked product of whey protein***, not a breakdown or decomposition product (partial hydrolysate) of milk whey protein.

In sharp contrast, the presently claimed methods involve adding a partial hydrolysate of milk whey protein to a milk material prior to coagulation. The partial hydrolysate of milk whey protein may be prepared by treating whey protein with a protease such as trypsin. Thus,

what is added to the milk in the present invention is a partial breakdown or decomposition product of whey protein.

There is no disclosure of the presently claimed process in Han et al. Moreover, a key step of the presently claimed methods involves treating the whey protein in a way which is just the opposite to the way described in Han et al.

Applicants submit that there is nothing in Monti et al which can cure the basic deficiencies of Han et al. Specifically, there is likewise no teaching in Monti et al which would suggest adding a partial hydrolysate of milk whey protein to a milk material prior to coagulation. Monti et al merely discloses that trypsin digestion is effective for the resolubilization of *heat-denatured* whey proteins. Moreover, Monti et al is unconcerned with increasing the amount of whey protein into a cheese product. In support of this assertion, Applicants cite the complete publication of Monti et al, a copy of which is being submitted herewith, as Exhibit A.

On page 2 of the Official Action, the position is taken that it would have been obvious to “use the trypsin as taught by” Monti et al in the process of Han et al, because “the use of trypsin serves to increase the solubility of whey protein and consequently makes it easier to incorporate into a cheese product.” However, this conclusion is not supported by the disclosures of the references.

Quite simply, there is no teaching in either of the cited references which would suggest that partial enzymatic digestion of whey proteins would be useful for increasing the incorporation of whey proteins into a cheese product. In fact, the primary reference, Han et al, discloses just the opposite. As explained above, Han et al disclose that it is by coagulating the whey protein that the incorporation in to a cheese product is increased. The coagulation

disclosed in Han et al is essentially just the opposite of the partial enzymatic hydrolysis disclosed in Monti et al. Thus, there is nothing in Han et al which would even remotely suggest that enzymatic hydrolysis would be useful for increasing the incorporation of whey protein into a cheese product. As also explained above, Monti et al is unconcerned with enhancing cheese yield. Since Monti et al is unconcerned with increasing the amount of whey protein into a cheese product, even the combined teachings of the cited references fail to suggest the presently claimed methods.

In any event, the skilled artisan would not be motivated to combine the disclosures of Han et al and Monti et al, because to do so would destroy the very heart of the primary reference, Han et al. Specifically, Han et al discloses:

The process includes *the significant step* that a dairy liquid fortified with whey protein is contacted with a transglutaminase to provide a modified dairy liquid containing whey protein products.

Abstract, emphasis added.

\* \* \*

This invention relates to a method that allows the incorporation of large amounts of whey protein into cheese. *The method involves the action of a transglutaminase on whey protein* to prepare cheese curd incorporating a significant proportion of whey protein.

Field of the Invention, col. 1, lines 6-10, emphasis added.

\* \* \*

The *principal requirement* of any transglutaminase employed in the instant invention is that it have the cross-linking activity discussed above.

Col. 7, lines 18-21, emphasis added.

\* \* \*

The known enzymatic function of transglutaminase is to catalyze the transfer of the  $\gamma$ -carboxamide group of a glutamyl residue in a protein or peptide to the  $\epsilon$ -amino of a lysyl residue of the same or a different protein or peptide. Without wishing to be bound by theory, if such reactions were to occur involving the whey proteins present in the first dairy liquid, glutamyl-lysyl side chain-side chain crosslinks would form between the protein components present, including crosslinks among and between the whey proteins (i.e., intra- or inter-molecular cross linking).

Col. 9, lines 11-20.

Thus, the entire point of Han et al is to use a transglutaminase to effect cross-linking of the whey protein to ultimately achieve incorporation of the whey protein into the cheese product. The trypsin partial hydrolysis of Monti et al is essentially the reverse of the transglutaminase cross-linking of Han et al. The use of trypsin in the method of Han et al would completely destroy the heart of this reference.

Moreover, there is nothing in the cited references, even in combination, which would suggest any advantage to be obtained by adding a partial hydrolysate of milk whey protein to a milk material prior to coagulation. In fact, it is the surprising discovery of the present inventors that the presently claimed methods for preparing cheese afford dramatic improvements in cheese yield.

In support of the assertion that the presently claimed methods result in dramatic improvements in cheese yield, the Examiner's attention is directed toward the results presented in Table 1, on page 27, of the specification. For the Examiner's convenience, the results given in Table 1 are repeated below:

Test solution: milk (whey decomposed material/TG)	Curd dry material weight (g)	lactose in dry curd (g)	Protein increase (g)
(a) Milk (non-added/non-added)	1.0475	0.318	0 (0%)
(b) Milk (non-added/added)	1.0714	0.306	+0.036 (5%)
(c) Milk (added/non-added)	1.2554	0.360	+0.166 (23%)
(d) Milk (added/added)	1.4331	0.506	+0.198 (27%)

Inspection of the results presented in Table 1 shows that addition of the partial hydrolysate of milk whey protein according to the present method, test solutions (c) and (d), afforded superior yields as compared to analogous test solutions in which the partial hydrolysate of milk whey protein was not added, test solutions (a) and (b). Applicants submit that there is no teaching in the cited references, even in combination, which would suggest the improved yields for the presently claimed methods, test solutions (c) and (d) in Table 1.

For all of these reasons, the rejection should be withdrawn.

Lastly, Applicants note that three separate Information Disclosure Statements ("IDSs") were filed on August 30, 2002; October 7, 2002; and January 29, 2003. However, to date Applicants have received no confirmation that these references have been considered. Accordingly, Applicants respectfully request that the Examiner forward initialed copies of the Forms PTO 1449 for all three IDSs with the next communication from the PTO. For the Examiner's convenience, new copies of the Forms PTO 1449 previously filed with the IDSs are being submitted herewith.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Stephen G. Baxter', written in a cursive style.

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